

**REMARKS/ARGUMENTS**

Reconsideration of this application is requested. Claims 2-4 and 8-17 remain pending in the application subsequent to entry of this Amendment. The examiner will note that claim 1 has been canceled and the subject matter of claims 5-7 incorporated into claim 2. The significance of this amendment is discussed below.

With regard to the Information Disclosure Statement and the examiner's comments on pages 2-3 of the Action, an expanded form PTO/SB/08A is submitted herewith which includes the first inventor's name of each of the published International "WO" applications and the number of pages in the International Search Report of October 13, 2005. This follows the examiner's suggestion on page 3 of the Official Action and applicants request that confirmation of review of these materials be indicated in the next communication from the Office.

The Action includes four *provisional* double-patenting objections against claims 1 and 2 on the basis of US applications US 10/566,972, US 10/572,306, US 11/658,857, and US 11/975,243 (it appears that this number contains a typographical error and should be US 11/795,243).

These are only provisional objections, since the cases raised are pending applications, not granted patents. Applicants will address these objections when claims are allowed in the subject application.

Turning to the substantive objections, the examiner has cited US 6,537,575 (referred to as "Firestone") as novelty-destroying in respect of claims 1 and 2. This document was considered in the corresponding European application. In the above amendment applicants have deleted claim 1 and incorporated claims 5-7 into claim 2.

The examiner indicates the disclosure of a composition of a lipid, a co-surfactant and a polymer amphiphile. However, the incorporation of the appropriate components from dependent claims 5, 6 and 7 into the independent claim now requires that components a), b) and c) be of specific types. In particular, swelling component b) be a polyoxyethylene component of the specified type, which is not disclosed in Firestone. In addition, it is clear from the discussion in columns 5-6 of Firestone that this document deals with lamellar materials and does not provide a composition comprising non-lamellar particles or forming non-lamellar particles on contact with an aqueous fluid. Thus the amended claims are novel over Firestone.

The examiner also cites US 6,593,294 (“Baru et al”) as novelty destroying to claim 1. This document is not cited against claim 2 and it appears that the amendment made above will also address this objection. Baru et al is directed at a neutral liposome composition and does not disclose a composition satisfying all the requirements of amended claim 2.

The Official Action contains only two rejections based on prior art and alleged anticipation which are addressed above. For completion of the record applicants submit that all claims are presently amended are inventive in view of Firestone and Baru et al, either alone or in combination. In particular, although Firestone provided an accidental disclosure relevant to original claim 1 prior to amendment, this citation does not address the problem to be solved by the present application. In particular, the present compositions relate to particles of non-lamellar phase which are of low toxicity and high stability. Such particles are not simply fragments of a bulk non-lamellar phase, but are the stable or meta-stable form of the composition. Firestone relates solely to bulk “gels” of non-lamellar phase and teaches nothing about compositions which form stable dispersions of non-lamellar particles. Although this is a highly effective strategy in itself, the compositions are not suitable for forming stable particulate dispersions of non-lamellar phase and thus Firestone does not address the problem of the present invention.

Baru et al is directed towards colloidal particles which can comprise components a) and c) of the current composition, but do not comprise component b). There is no teaching of a composition according to amended claim 2, nor of its advantages in terms of stability and toxicity.

The problem to be solved by the present invention may be seen as providing non-lamellar particles which are inherently stable and of low toxicity. The problem of combining stability as non-lamellar particles with low toxicity is solved in the present invention by combining the specified components, having three specific necessary functions, the particular proportions specified.

Prior to the present invention, so-called mono-acyl lipids were widely believed necessary for producing stable non-lamellar particles, and none of the cited documents provides any teaching to indicate that such would be possible without a mono-acyl component. This is, however clearly demonstrated in the present case where stable particles in the absence of mono-acyl components are demonstrated.

All outstanding issues have been addressed and this application is in condition for allowance. Should any minor issues remain outstanding, the Examiner should contact the undersigned at the telephone number listed below so they can be resolved expeditiously without need of a further written action.

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 14-1140.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

By: /Arthur R. Crawford/  
Arthur R. Crawford  
Reg. No. 25,327

ARC:eaw  
901 North Glebe Road, 11th Floor  
Arlington, VA 22203-1808  
Telephone: (703) 816-4000  
Facsimile: (703) 816-4100